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APPLICATION

Of

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For

UTILITY PATENT APPLICATION

On

BLOOD PRESSURE SENSOR APPARATUS

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TITLE: BLOOD PRESSURE SENSOR APPARATUS

CROSS-REFERENCE TO RELATED APPLICATIONS

This application for a utility patent claims the benefit of U.S. Provisional Application No. 60/458,660, filed March 28, 2003.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH

Not Applicable

BACKGROUND OF THE INVENTION

FIELD OF THE INVENTION:

This invention relates generally to a blood pressure sensor apparatus, and more particularly to a blood pressure sensor apparatus that can be implanted into a patient and used to regularly report the blood pressure of the patient.

DESCRIPTION OF RELATED ART:

The monitoring of blood pressure by caregivers has become a well-characterized biomonitoring tool. Hypertension, hypotension, shock and circadian rhythm are some examples of conditions monitored via blood pressure. In most cases, the usage of a sphygmomanometer and a pressure cuff suffice. But in cases where long-term, mobile, non-tethered, and/or physician-free patient monitoring is required, a more elaborate and implantable system may be needed.

The foremost requirement for implantation is the size of the device. The implant should not impart any physiological disturbance nor should it present any substantial inconvenience. Furthermore, the device may only protrude into a blood vessel a very small amount, because the introduction of a significant disturbance into a blood vessel can cause health problems.

Supplying power to the device and rate of power consumption are also important factors because battery size and replacement are critical limiting factors to the miniaturization and operation of the device. Finally, a means of transmitting the signal is an integral part of the implant as well as a technique to encapsulate the entire device for the bilateral protection of the physiology and the implant.

SUMMARY OF THE INVENTION

The present invention teaches certain benefits in construction and use which give rise to the objectives described below.

The present invention provides an implanted sensor for measuring pressure in a conduit through a wall. The implanted sensor includes a main body and a probe. The main body includes an implant inductor. The probe has capacitor electronically connected to the implant inductor. The probe is adapted to fit through the wall so that the capacitor can sense pressure in the conduit.

A primary objective of the present invention is to provide an implanted sensor having advantages not taught by the prior art.

Another objective is to provide an implanted sensor that can readily be positioned outside of a conduit such as a blood vessel without undue trauma to the patient.

Another objective is to provide an implanted sensor that includes a probe that can be positioned through the blood vessel so that blood flow within the blood vessel is not significantly impeded or disrupted.

A further objective is to provide an implanted sensor that can be installed in a single procedure and then take continuous blood pressure measurements without further surgical procedures being required.

Other features and advantages of the present invention will become apparent from the following more detailed description, taken in conjunction with the accompanying drawings, which illustrate, by way of example, the principles of the invention.

BRIEF DESCRIPTION OF THE DRAWING

The accompanying drawings illustrate the present invention. In such drawings:

FIGURE 1 is a perspective view of one embodiment of a blood pressure sensor apparatus;

FIGURE 2 is a sectional view thereof taken along line 2-2 in Figure 1;

FIGURE 3 is a block diagram thereof;

FIGURE 4 is a bottom perspective view of an implanted sensor;

FIGURE 5 is a side elevational view thereof, a portion of the implanted sensor being shown broken away to illustrate first and second electrodes;

FIGURE 6 is a top perspective view of the implanted sensor illustrating a plurality of bores in a top surface of the implanted sensor;

FIGURE 7 is a perspective view of the blood pressure sensor apparatus transmitting data to a personal transmitter/receiver that is operatively attached to a computer; and

FIGURE 8 is a perspective view of the blood pressure sensor apparatus transmitting data through a cellular transmitter/receiver to a data center.

DETAILED DESCRIPTION OF THE INVENTION

The above-described drawing figures illustrate the invention, a blood pressure sensor apparatus **10** for periodically measuring the blood pressure of a patient.

As shown in Figs. 1-2, the blood pressure sensor apparatus **10** includes an implanted sensor **20** and an external reader **30**. The implanted sensor **20** is adapted to be implanted in the patient for sensing the blood pressure. The external reader **30** is adapted to be positioned adjacent the implanted sensor **20**, outside the body of the patient, and inductively coupled to the implanted sensor **20** to periodically read the blood pressure of the patient.

In the preferred embodiment, the external reader **30** is a wristwatch that can be conveniently worn by the user around his or her wrist. However, in alternative embodiments, the external reader **30** could be shaped to be worn around any portion of the body that is suitable for the implanted sensor **20**. While it is currently preferred that the external reader **30** be adapted to be worn for significant periods of time, the external reader **30** could also be a hand-held scanner that is not worn, but is periodically positioned adjacent the patient to take blood pressure readings.

While we discuss the use of the blood pressure sensor apparatus **10** to measure the blood pressure of a patient, typically a human, the blood pressure sensor apparatus **10** can be used to measure the blood pressure in any animals, or indeed any closed system that includes a fluid flow whose pressure may be measured. Such alternative applications of the present apparatus should be considered within the scope of protection of the present patent.

As shown in Fig. 3, the implanted sensor **20** includes an implant circuit **22** that includes a capacitor **C** electronically connected to an implant inductor **L1**. The external reader **30** includes an external circuit **32** that includes a power supply **34** electronically coupled to an external inductor **L2**.

The implanted sensor **20** further includes a means for determining the blood pressure at the capacitor **C** using the implant inductor **L1** and the external inductor **L2**. The means for determining the blood pressure includes sweeping the external inductor **L2** through a range of frequencies using an oscilloscope **38** and measuring a dip at a specific frequency, the specific frequency being determined by the capacitance of the capacitor **C**, which in turn is determined by the blood pressure exerted against the capacitor **C**. The oscilloscope **38** is adapted to perform a "grid-dip" sweep wherein the external reader **30** sweeps through a range of frequencies until it reaches a point that resonates with the implant circuit **22** and the oscilloscope measures a "dip.". Since the frequency of resonance will vary depending upon the capacitance of the capacitor **C**, and thus the patient's blood pressure, it is possible to measure the blood pressure of the patient from the external reader **30** with reference to a simple calibration table.

The implant circuit **22** also includes a means for reporting the results of the "grid dip" sweep. In one embodiment, as shown in Figs. 1 and 3, the external reader **30** includes a display **40**, such as an LCD screen or similar feature, then enables the user to read the results of the measurements being taken. In this embodiment, the external circuit **32** includes a processor **42**, a memory **44**, and a keypad **46** for enabling the user to control the external reader **30**. The inclusion of these additional elements enables the user to store multiple readings within the memory **44** for later review and/or download to a computer **52** using techniques well known in the art. Since the construction of such a circuit is well known to one skilled in the art, given the teachings of this invention, the specific construction of the external reader **30** is not described in greater detail herein.

As shown in Fig. 3, the external reader **30** can also include a transmitter/receiver **48** for transmitting the measurements taken by the external reader **30**. In one embodiment, shown in Fig. 7, the transmitter/receiver **48** transmits data to a personal transmitter/receiver **50** that is electronically connected to a computer **52**. Upon a query from the computer **52**, which could be located in a patient's home or in a doctor's office, the transmitter/receiver **48** of the external reader **30** could transmit the readings that were taken previously and stored in the memory **44**.

In another embodiment, shown in Fig. 8, the transmitter/receiver **48** could transmit the data using cellular technology through a cellular transmitter/receiver **54** to a data center **56** for collection, analysis, and reporting. Obviously, many equivalent communications systems

could be used, including satellite or IR transmissions, communications through a global computer network such as the Internet®, or a local area network. Any of these or similar reporting systems should be considered within the scope of the present invention.

Of course, communications between the external reader **30** and the computer **52** or the data center **56** would be two-way, thereby enabling many options in taking, reporting, and responding to blood pressure measurements. For example, if a patient's blood pressure were to get so high or so low as to threaten the health of the patient, and immediate warning could be sent to the patient, as well as the patient's doctor and/or a local ambulance dispatcher. The blood pressure sensor apparatus **10** could also be integrated with other systems, such as a medication injection device (not shown), that would automatically administer treatment in response to high or low blood pressure.

As shown in Figs. 4-5, the implanted sensor **20** preferably includes main body **58** and a probe **62** that extends outwardly from the main body **58**. The main body **58** includes the implant inductor **L1** and any other electronics or other useful structural features. In one embodiment, the main body **58** is generally cylindrical and the conductive material that forms the implant inductor **L1** formed in a coil around a perimeter **60**. Due to the minimum size requirements of the implanted inductor **L1**, the main body **58** is adapted to remain outside the blood vessel **12** of the patient, thereby minimizing the potentially harmful impact of the implanted sensor **20** on the blood flow of the patient.

The probe **62** is adapted to extend into the blood vessel **12** for the purpose of measuring the pressure in the blood vessel **12**. The probe **62** must be small enough to prevent thrombosis or other health complications in the patient. In the preferred embodiment, the probe **62** includes a neck portion **64** that extends outwardly to a head portion **66**. The neck portion **64** is preferably cylindrical and includes an internal saline chamber **68**. The head portion **66** is shaped to penetrate through and then lockingly engage the blood vessel **12**. The head portion **66** is preferably generally conical in shape. A terminus **70** of the head portion **66** forms an aperture **72** that is covered with a flexible membrane **74**. The internal saline chamber **68** is filled with saline or other biocompatible fluid or equivalent material that is contained within the internal saline chamber **68** by the flexible membrane **74**.

The first electrode **26** forms the rear of the internal saline chamber **68** opposite the flexible membrane **74**. The second electrode **28** is positioned a suitable distance from the first electrode **26**, separated by a gap **76** that is suitable to form the capacitor **C**. The first electrode **26** is preferably a capacitive membrane formed of a highly doped silicon in conjunction with highly insulating support layers **80**. The highly insulating support layers **80** are useful in limiting parasitic capacitance, which may otherwise interfere with accurate pressure measurement. Those skilled in the art can devise many alternative forms of the first electrode **26**, and such alternative structures should be considered within the scope of the present invention.

In operation, pressure from the blood vessel **12** causes a deflection of the flexible membrane **74**, which is transmitted through the saline in the internal saline chamber **68** to the capacitive

membrane **26**, which in turn is deflected. When the capacitive membrane **26** is deflected, this changes the size of the gap **76** between the capacitive membrane **26** and the second electrode **28**, thereby altering the capacitance of the capacitor **C**. Changes in the capacitance cause a change in the frequency at which the external reader **30** measures a "dip" in the oscilloscope **38**, as described above.

The head portion **66**, shown in Figs. 4-5, is adapted to facilitate the penetration of the probe **62** through a vessel of the patient so that the flexible membrane **74** is positioned inside the blood vessel **12**, as shown in Fig. 2. The neck portion **64** is adapted to extend through the blood vessel **12** so that the main body **58** is located outside the blood vessel **12**, thereby minimizing any interference that the implanted sensor **20** may cause within the blood vessel **12**. The flexible membrane **74** is disposed on an outside surface **78** of the implanted sensor **20** so that the flexible membrane **74** is exposed to the patient's blood once the implanted sensor **20** has been implanted in the patient.

The implanted sensor **20**, and the capacitive membrane **26**, are preferably constructed of silicon and formed using MEMS manufacturing techniques known in the art. By utilizing MEMS construction techniques, the implanted sensor **20** can be made extremely small, thereby minimizing the problems that can occur when a sensor is implanted in a patient's body. In one embodiment, as shown in Fig. 4, the implanted sensor **20** can be coated with a biocompatible coating **82**, or housed within a suitably biocompatible structure, to prevent biocompatibility problems once the implanted sensor **20** has been implanted into the patient.

The biocompatible coating **82** may also include embedded anti-coagulants (not shown) that are released throughout the intended lifetime of the sensing unit.

As shown in Fig. 6, an upper surface **84** of the implanted sensor **20** may include a plurality of bores **86** or "bosses." The plurality of bores **86** function to increase the signal and improve the linear response. The plurality of bores **86** are preferably evenly spaced to increase their effectiveness.

ALTERNATIVE SENSOR MEANS

While the inductor/capacitor system that is described herein is currently the preferred sensor means, alternative sensor means (not illustrated herein) could also be utilized. For example, the sensor means could be provided by a piezoelectric sensor, a strain gauge, or another sensor known to those skilled in the art.

These alternative sensor means could be powered by the inductor system described above, be miniature batteries operably installed in the main body **58** of the implanted sensor **20**, or by a resonant circuit that receives power from an external signal and then returns a return signal that reports a reading taken by the sensor means. Such alternatives should be considered within the scope of the present invention.

METHOD OF IMPLANTATION AND USE

The implanted sensor **20** is preferably to be implanted in the distal antebrachial region (forearm) adjacent the Ulnar or Radial arteries, since the thickness of integumentary tissues is relatively and consistently thin across this portion of the body. This site will also permit for easy placement of the external reader **30**, in the embodiment of a wristwatch. Of course, those skilled in the art could devise alternative locations for the implantation and monitoring of the implanted sensor **20**, and placement in an alternative location should be considered within the scope of the present invention.

The implanted sensor **20** preferably utilizes the passive system described above to eliminating any in-vivo power source requirement. The capacitive sensor system described above measures blood pressure by measuring the deflection of the capacitive membrane **26** that provides one electrode of a capacitive pair. The pressure sensor capacitance is part of an electrically resonant LC circuit load where L represents inductance and C represents capacitance. An alternating signal generated by the external reader **30** is transmitted at various frequencies to 'sweep' a response from the implant passive circuit. The transmitted input signal is coupled into the passive circuit at the LC resonant frequency, f, determined by:

$$f = \frac{1}{2\pi}\frac{1}{\sqrt{LC}}$$

There is a non-ideal resistance, $\boldsymbol{R}$, in the $\boldsymbol{LC}$ passive circuit that degrades the resonance response. Along with the membrane deflection with pressure, the quality factor, $\boldsymbol{Q}$, is a measure of the device sensitivity and is given by:

$$Q = \frac{2\pi fL}{R}$$

The objective is to design the implant circuit **22** with minimum resistance. Coil design, material selection, and interconnection to the pressure sensor are areas where minimal resistance is a critical design parameter.

If the capacitive membrane **26** is 1mm x 1mm with a 1 um gap **76**, the capacitance is approximately equal to 8.8 picofarads. A realizable mini-inductor can approach 1 microHenry. These values then estimate that the electronic detection circuit will operate in the vicinity of 50 mHz.

Sufficient pressure sensitivity and inductance can be housed in an implanted sensor 20 with dimensions roughly 5 mm in diameter and 0.3 mm in thickness. A small die size conflicts with larger membranes and inductor coils for greater sensitivity and lower "tank" frequency. (Inductance is inversely proportional to the square of the frequency.) The sensitivity of the sensor is governed by the flexibility of the capacitive membrane **26**. A thin capacitive membrane **26** of large width provide the greatest sensitivity but can lead to nonlinearity problems. This effect is caused by the introduction of tensile stresses in the capacitive membrane **26** under load. Specialized "bossed" geometries, described above and in Figs. 4-5, can be implemented for improved linear response.

Careful attention must be made to the electrical properties of the sensor structure. Since capacitance change is the measured property, the overall parasitic capacitances, Cp within the system must be kept at reasonable levels to obtain adequate sensitivity. For a capacitive signal-detecting circuit, the greatest sensitivity is achieved by maximizing the factor:

$$\frac{1}{C_x + C_0 + 2C_p} \frac{\partial(C_x - C_0)}{\partial P}$$

where C_x is the capacitor C sensitive to the pressure, P. The reference capacitor C is designated by C_0. Capacitive membrane **26** materials such as highly doped silicon in conjunction with highly insulating support layers **80** can effectively limit the parasitic capacitance.

One of the key challenges is the accessibility of the blood to the pressure sensor. Due to the small size of the 3 mm diameter vessels, it is imperative that the implanted sensor **20** be as small as possible in order to facilitate insertion, minimize flow impedance and prevent thrombosis. Thus, the use of the probe **62** to extend into the blood vessel **12** while leaving the implanted sensor **20** outside the vessel solves many problems. This approach addresses issues concerning flow impedance, deployment, retrieval, and arterial embolism due to sensor detachment.

To avoid occlusion, the tip of the cannula can be capped off with a flexible membrane **74** so that pressure is translated across the membrane to a saline solution column on the opposite side. This design will communicate the pressure to the sensor external to the artery.

While the invention has been described with reference to at least one preferred embodiment, it is to be clearly understood by those skilled in the art that the invention is not limited thereto, but includes all similar, equivalent, or obvious alternatives that could be devised without undue experimentation by one of reasonable skill in the art.